Docket No.: HO-P01952US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Julie A. Bearcroft, et al.

Application No.: 09/517,981

Group Art Unit: 3738

Filed: March 3, 2000

Examiner: B. Pellegrino

For: SHAPED PARTICLE AND COMPOSITION FOR BONE DEFICIENCY AND METHOD OF MAKING THE PARTICLE

DECLARATION UNDER 37 CFR §1.132

Dear Sir:

I, Michael B. Cooper, do hereby depose and say as follows:

1. I am a United States citizen residing at 2800 Manning Circle South, Nesbit, MS 38651.

2. I am an employee of the assignee of the above-referenced patent application, I am an inventor of said application, and I have read the contents of said application.

3. I am a Manager of Research Projects at Smith + Nephew, Inc. I am skilled in the area of bone substitute methods and compositions. A resume describing my experience is attached to this declaration.

Claims 1-4, 9-11, 14-16, 20-22, 26, 64, 65, 69, 70, and 73-80 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,178,201 ("Ahlers") alone and in combination with other references. I respectfully disagree.

I am one of skill in the art of bone graft substitute compositions and methods. A skilled artisan recognizes that the intent of Ahlers is to provide a permanent open structure on an implant having a large surface area for the purpose of avoiding juxtaposition of a flat metal piece of implant against bone. The purpose of Ahlers is not to repair bone but to provide for a

means to juxtapose a permanent implant next to bone. Ahlers concerns providing implants utilizing "surface structures of the implant...[that] are discrete and so stable, that an additional treatment of the positive pattern is not necessary..." (col. 2, lines 30-32). Ahlers teaches the particles having three pins bonded to the basic pattern (at least at col. 3, lines 3-4), and as an entire structural entity being the particles bonded to the implant backbone, this would be utilized for the duration of the lifetime of the individual. ***A skilled artisan recognizes that implant compositions and methods are a completely different field of use than the bone healing and bone graft substitute field of our invention, so one of skill in the art would not utilize technology in one field as a catalyst for ideas for the other field, particularly when the end results are conflicting (see below). Therefore, one would <u>not</u> consider this relevant in the field of bone graft substitutes in which it is useful to have a temporary scaffold in a defect in which the scaffold goes away with time.*** While the shape of the particles that are bonded to the implant may be similar, Ahlers does not teach or suggest that this shape separate and apart from the implant or bonded to the implant would be suitable for repairing bone to its natural state, which is the purpose of a bone graft substitute such as our invention.

The objective of Ahlers and the objective of our invention are wholly different, and the design of the two inventions provide not only dissimilar but discordant end results. Whereas the design of our invention provides for restoration of bone tissue and bone ingrowth, the design of Ahlers' invention, comprising as a whole the particles bonded to an implant, provides for a solid outer surface of an implant to impart a means to attach to a nearby bone. Furthermore, our invention utilizes the particles as loose granules for a temporary scaffold, whereas Ahlers utilizes a fixed immobile bipartite structure comprised of these particles bonded to the solid implant. Given that the bonded particles would be insufficient for the purpose of providing temporary scaffolding to fill a bone defect, for example, a skilled artisan would not consider our invention obvious, particularly when the bonded fixed particle structure is incapable of filling an irregularly shaped bone defect, in contrast to our invention.

Consistent with the teaching of facilitating implantation of a permanent implant, Ahlers does not teach using resorbable materials to replace missing bone with healthy bone. Ahlers teaches utilizing materials that are not resorbable, such as wax, polypropylene, polyethylene, or PMMA, all of which are inappropriate for use in a bone graft substitute. In fact, a skilled artisan would <u>not</u> recognize our invention as obvious when Ahlers teaches materials that not

only would not recruit bone cells, such as for our field of use in bone graft substitutes, but the materials are not known to be osteoconductive; that is, bone cells are not attracted to these inhospitable materials, and bone would not be laid down surrounding them.

In summary, the objective in optimizing shapes of bone graft substitute particles, such as with our invention, is to repair bone to its original state where there is a void of bone. This would require biocompatible, resorbable materials that attract osteoblasts or osteoblast-like cells such that these cells will lay down bone and continue to lay down new bone as the bone graft material resorbs. This is definitely not taught or suggested in Ahlers, and Ahlers' teachings do not lend themselves to be applied with other bone repair or augmentation patents to achieve this goal. By nature of using an implant, such as with Ahlers' implant, a medical provider removes bone and cuts a defect upon implantation of the implant; the defect in the bone will never heal. However, we heal an existing defect through resorption of our bone graft substitutes and recruitment of bone cells. These are conflicting fields of use, and a skilled artisan would not make the connection between Ahlers bonded particle-implant structure and our mobile bone graft substitute array configuration.

Based on the teachings of Ahlers, it is not obvious to utilize Ahlers' invention in combination with Black's teaching to develop a bone graft substitute, and certainly not in combination with Chen or Barralet. One skilled in the art in the development of a bone graft substitute would not utilize ideas from implant fixation techniques separately or in combination with bone repair or augmentation patents.

4. I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 5-10-04

Michael B. Cooper